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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/648,676	05/16/96	LEADER	M 2227-006

EXAMINER

A1M1/0218

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ART UNIT	PAPER NUMBER
1102	12

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 12-2-97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-17, 19-22 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-17, 19-22 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-498/40011

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-13, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Knudson etal or Brown etal and/or Europe '629.

Betts discloses a sensing assembly comprsing an array of sensors located on one side of a substrate 111. A plurality of conductors are located on the opposite side of the substrate each electrically connected with an electrode of a sensor by a laser induced thru hole that is filled with conductive material. An encasement covers the sensor assembly and has at least one channel between inlet and outlet means for the flow of an analyte and has an opening for exposing the conductors. See col. 2, line 37 to col. 3, line 40; col. 6, line 21 to col. 8, line 46; col. 11, lines 21-53; col. 19, line 29 to col. 22, line 6. Applicant's claims differ by calling for the thru hole to be located directly under a sensor and to have a diameter of about .002-.006 inch.

Knudson disclose a thru hole 120 located directly beneath a sensor (col. 7, line 62 to col. 8, line 13) having a diameter of about 2 mm (col. 5, line 32). Brown discloses a thru hole in substrate 25 directly beneath sensor 27 (col. 6, lines 28-50) having a cross section area of about 600 square microns (col. 6, line 53), which translate to about a diameter of about 15 microns. Europe discloses electrode conductor thru holes with diameters of up to 100 microns, which are clearly within applicant's range. See col. 2, line 4 to col. 4, line 13; col. 6, line 47.

It would have been obvious for Betts to locate the thru hole directly beneath the sensors in view of the secondary references so as to permit the location of the conductors on the side of the substrate away from contact with the analyte. This would tend to avoid corrosion of the conductors. It would also have been obvious for Betts to adopt the thru hole dimension of Europe, since size is a matter of design choice.

Claims 4, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Knudson etal or Brown etal and/or Europe '629 and Grubb.

These claims further differ by calling for the interal electrolyte of the reference electrode to be in the gel form.

Grubb discloses a gel electrolyte for a reference electrode to be well-known. See col. 2, line 25.

It would have been obvious for Betts to adopt a gel electrolyte in view of Grubb, because a gel is immobilized and would prevent sloshing and thus be position-insensitive.

Claims 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Knudson etal or Brown etal and/or Europe '629 and Buzza.

These claims further differ by calling the flow channel to have a dome shape near the oxygen sensor.

Buzza discloses a flow channel having a dome shape near the measuring end 246 of an oxygen sensor 18. See col. 9, line 13.

It would have been obvious for Betts to enlarge the flow channel to a dome shape so as to accommodate the configuration of the sensors.

Claims 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Betts etal in view of Knudson etal or Brown etal and/or Europe '629 and Pace '410 and Kuhn etal.

These claims further differ by calling for the sensors to be sensitive to various ions and to include a hematocrit sensor.

Pace in the table at column 12 discloses sensors sensitive to these ions. Kuhn discloses a hematocrit sensor to be old. See col. 1, line 6.

It would have been obvious for Betts to adopt the sensors of Pace and Kuhn, since it would be desirable to measure for all these ions with a single assembly. Also, the incorporation of conventional features from analogous prior art is within the skill of the art.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is not evident what basis exists in the original disclosure for "the electrical conductors have a diameter of about ten times the diameter of the thru-holes".

Claims 6, 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is unclear what function is served by the third cell 1213. In the specification, page 35, the middle paragraph appears to suggest that this flow cell is provided merely for the purpose of reducing the amount of the encasement material adjacent flowcell 1201. Is this really the function of flow cell 1213?

Claims 1-17, 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 8 and claim 19, line 10, "inches" should be singular, since the values are less than one. Same claims, lines 8 and 9 respectively, there is a zero before the .002 value, but not before the .006 value. A zero is optional, but should be consistent for both values.

Claims 6 and 20, "the third cell" is vague, when only a reference cell has been recited.

Claim 7, "millimeters"; col. 8, "inches"; claim 10, "inches" (first and third occ.); claim 13, "inches"; claim 21, "inches" and "millimeters" should be singular since the values are less than one.

In the specification, page 2, line 23, a period is missing.

The examiner can be reached at 703-308-3329. Any inquiry of a general nature should be directed to the receptionist at 703-308-0661.

T. T

Ta Tung

Primary Examiner

Art Unit 1102